OCT 25 2001

K013272

Bayer Diagnostics

ASC and ADVIA Centaur Theophylline 2 Immunoassays

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

4.1 Submitter Information

Contact person:	Kenneth T. Edds Ph.D.
Address:	Bayer Diagnostics Corporation 511 Benedict Ave. Tarrytown NY 10591 Phone: 914-524-2446 FAX: 914-524-2500 e-mail: ken.edds.b@bayer.com

4.2 Modified device information

Proprietary name:	ADVIA Centaur and ACS Theophylline 2 Immunoassays
Common name:	Theophylline immunoassay

4.3 Predicate device:

Name:	ACS Theophylline Assay
510(k) Number:	K951169
Original submitter:	Ciba Corning Diagnostics Corp 63 North Street Medfield MA 02052

4.4 Device Description

The ACS and ADVIA Centaur Theophylline 2 are competitive chemiluminescence immunoassays are intended for the quantitative determination of theophylline in human serum and plasma. Theophylline in the patient sample, calibrators, standards and controls competes with acridinium ester-labeled theophylline in the Lite Reagent for a limited amount of monoclonal mouse anti-theophylline antibody, which is covalently coupled to paramagnetic particles in the Solid Phase. Following incubation, unreacted acridinium ester-labeled theophylline and unreacted theophylline from the sample are washed from the reaction mixture. The chemiluminescence of the reacted, labeled theophylline is measured in a luminometer. The measured chemiluminescence is inversely proportional to the quantity of theophylline in the sample.

4.5 Statements of Intended Use

- **ACS Theophylline 2**

"For the quantitative determination of theophylline in serum or plasma using the ACS:180 Automated Chemiluminescent Systems. For In Vitro diagnostic use."

- **ADVIA Centaur Theophylline 2**

"For in vitro diagnostic use in the quantitative determination of theophylline in serum or plasma using the ADVIA Centaur System."

4.6 Summary of Technological Characteristics

The ACS and ADVIA Centaur Theophylline 2 Immunoassays are similar to ACS Theophylline assay (the predicate device) in the indications for use, format, performance characteristics, and results. The ACS and ADVIA Centaur Theophylline 2 immunoassays and the ACS Theophylline differ in method used to couple the anti-theophylline monoclonal antibody to the solid phase. In the Theophylline 2 assays, the antibody is labeled with fluorescein isothiocyanate (FITC) and bound to an anti-FITC antibody covalently coupled to the particles. In ACS Theophylline, goat anti-mouse IgG, covalently bound to the particles, binds the anti-theophylline antibody.

4.7 Method Comparison

Substantial equivalence of the ACS and ADVIA Centaur Theophylline 2 assay to the ACS Theophylline is seen.

These correlation studies demonstrates that the ACS:180 & ADVIA Centaur Theophylline 2 assay is equivalent to each other the unmodified predicate devices, the Bayer Corporation ACS Theophylline assay.

Reference Assay	Test Assay	Slope	Intercept	Correlation Coefficient (r)	N
ACS Theophylline	ADVIA Centaur Theophylline 2	0.94	1.36	0.99	138
ACS Theophylline	ACS Theophylline 2	1.00	-0.24	0.99	138
ACS Theophylline 2	ADVIA Centaur Theophylline 2	1.05	-0.9	0.99	138

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 5 2001

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k013272
Trade/Device Name: Bayer Diagnostics ACS: 180 and ADVIA Centaur Theophylline Assay
Regulation Number: 21 CFR 862.3880
Regulation Name: Theophylline test system
Regulatory Class: Class II
Product Code: KLS
Dated: September 27, 2001
Received: October 1, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013272 Page 1 of 1

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur Theophylline Assay

Indications for Use:

The ACS:180 and ADVIA Centaur Theophylline 2 Immunoassays are competitive, chemiluminescence immunoassay for the quantitative determination of theophylline in human serum and plasma for use on the automated analyzer marketed by Bayer Corporation. Theophylline (1,3-dimethylxanthine) is a potent bronchodilator and respiratory stimulant that is used for the treatment of asthma. Monitoring a patient's theophylline level is very important in reducing the risks of over- or under-medication resulting from the individual variability of theophylline absorption, metabolism and clearance and the narrow therapeutic index. The ACS and ADVIA Centaur Theophylline 2 immunoassays are used as an aid to monitor a patient's theophylline level.

The ACS and ADVIA CentaurTheophylline 2 assays are an enhanced version of the current ACS Theophylline assay. The enhancements are aimed at providing a more versatile assay in the clinical laboratory.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K013272

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**